

EXPRESS MAIL NO. EV887981045US

Sheet 1 of 1U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
480208.408APPLICATION NO.
09/896,812SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

APPLICANTS

Thomas D. Madden et al.

FILING DATE
June 29, 2001GROUP ART UNIT
1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
lu	AA	5,741,516	04/21/98	Webb et al.	424	450	
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AK					
	AL					
	AM					
	AN					
	AO					

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AP		
	AQ		
	AR		

EXAMINER

Kulu

DATE CONSIDERED

2/07

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).



AUG 21 2003

TECH CENTER 1600/2900

PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Page 1 of 3

Complete if Known

Application Number	09/896,812
Filing Date	June 29, 2001
First Named Inventor	Madden, Thomas D.
Art Unit	1615
Examiner Name	Gollamudi S. Kishore
Attorney Docket Number	016303-008030US

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-5,023,087	06/11/1991	Yau-Young	
	AB	US-5,552,156	09/03/1998	Burke	
	AC	US-5,837,282	11/17/1998	Fenske et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code	Number ⁴	Kind Code ⁵ (if known)				
	AD	PCT	WO 95/08986	A1	04/08/1995	SmithKline Beecham Corporation		<input type="checkbox"/>
	AE	PCT	WO 98/17256	A1	04/30/1998	Kirpotin, Dmitri		<input type="checkbox"/>
	AF	PCT	WO 99/51202	A2	10/14/1999	Sequus Pharmaceuticals, Inc.		<input type="checkbox"/>
	AG	PCT	WO 00/23052	A1	04/27/2000	Alza Corporation		<input type="checkbox"/>

Examiner
SignatureDate
Considered

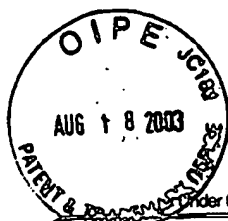
2/07

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

AUG 18 2003
TECH CENTER 1600/2000

PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Page 2 of 3		Complete If Known	
		Application Number	09/896,812
		Filing Date	June 29, 2001
		First Named Inventor	Madden, Thomas D.
		Art Unit	1615
		Examiner Name	Gollamudi S. Kishore
		Attorney Docket Number	016303-008030US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
W	• AH	BURRIS III et al., "Activity of topotecan, a new topoisomerase I inhibitor, against human tumor colony-forming units in vitro," <i>Journal of the National Cancer Institute</i> 84(23):1816-1820 (1992)	
	• AI	CLEMENTS et al., "Antiangiogenic potential of camptothecin and topotecan," <i>Cancer Chemother. Pharmacol.</i> 44:411-416 (1999)	
	• AJ	EMERSON et al., "In vivo antitumor activity of two new seven-substituted water-soluble camptothecin analogues," <i>Cancer Research</i> 55:603-609 (1995)	
	• AK	ERICKSON-MILLER et al., "Differential toxicity of camptothecin, topotecan and 9-aminocamptothecin to human, canine, and murine myeloid progenitors (CFU-GM) in vitro," <i>Cancer Chemother. Pharmacol.</i> 39:467-472 (1997)	
	• AL	GROCHOW et al., "Pharmacokinetics and pharmacodynamics of topotecan in patients with advanced cancer," <i>Drug Metabolism and Disposition</i> 20(5):708-713 (1992)	
	• AM	HARDMAN et al., "Efficacy of treatment of colon, lung and breast human carcinoma xenografts with: Doxorubicin, cisplatin, irinotecan or topotecan," <i>Anticancer Research</i> 19:2269-2274 (1999)	
	• AN	HSIANG et al., "Identification of mammalian DNA topoisomerase I as an intracellular target of the anticancer drug camptothecin," <i>Cancer Research</i> 48:1722-1726 (1988)	
	• AO	MADDEN et al., "The accumulation of drugs within large unilamellar vesicles exhibiting a proton gradient; a survey," <i>Chemistry and Physics of Lipids</i> 53:37-48 (1990)	
	• AP	MADDEN et al., "Encapsulation of topotecan in lipid-based carrier systems. Evaluation of drug stability and plasma elimination in a murine model, and comparison of antitumor efficacy against murine L1210 and B16 tumors," <i>Proc. of ASCO</i> , 17:abstract #754 (1998)	
	• AQ	MAYER et al., "Characterization of liposomal systems containing doxorubicin entrapped in response to pH gradients," <i>Biochimica et Biophysica Acta</i> 1025:143-151 (1990)	
	• AR	McCABE et al., "Comparative activity of oral and parenteral topotecan in murine tumor models: Efficacy of oral topotecan," <i>Cancer Investigation</i> 12(3):308-313 (1994)	
	• AS	O'LEARY et al., "Antiangiogenic effects of camptothecin analogues 9-amino-20(S)-camptothecin, topotecan, and CPT-11 studied in the mouse cornea model," <i>Clinical Cancer Research</i> 5:181-187 (1999)	
	• AT	ORMROD and SPENCER, "Topotecan: A review of its efficacy in small cell lung cancer," <i>Drugs</i> 58(3):533-551 (1999)	
W	• AU	TARDI et al., "Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models," <i>Cancer Research</i> 60:3389-3393 (2000)	

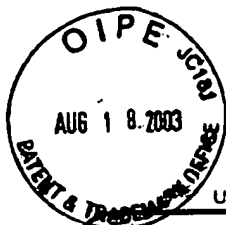
Examiner Signature	Kishore	Date Considered	2/07
--------------------	---------	-----------------	------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

60015659 v1



AUG 21 2003

TECH CENTER 1600/2900



PTO/SB/08B (04-03)


Approved for use through 04/30/2003. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known			
		Application Number	09/896,812		
		Filing Date	June 29, 2001		
		First Named Inventor	Madden, Thomas D.		
		Art Unit	1615		
		Examiner Name	Gollamudi S. Kishore		
Page	3	of	3	Attorney Docket Number	016303-008030US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AV	THOMPSON <i>et al.</i> , "Animal models for studying the action of topoisomerase I targeted drugs," <i>Biochimica et Biophysica Acta</i> 1400:301-319 (1998)	
	AW	WALL <i>et al.</i> , "Plant antitumor agents. I. The isolation and structure of camptothecin, a novel alkaloidal leukemia and tumor inhibitor from <i>Camptotheca acuminata</i> ," <i>Journal of the American Chemical Society</i> 88(16):3888-3890 (1966)	

Examiner Signature		Date Considered	2/07
-----------------------	---	--------------------	------

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Applicant's unique citation designation number (optional). ³ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.88. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.